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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,691	06/20/2003	Jean-Pierre Sommadossi	06171.IDX 1007 CON1	1388

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EXAMINER	
OWENS JR, HOWARD V	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,691	SOMMADOSSI ET AL.	
	Examiner	Art Unit	
	Howard V. Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 130-143 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 130-143 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/9/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 130-133 and 135-143 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 6,777,395, Bhat et al. (Bhat).

Claim 130 is drawn to a method for treating hepatitis C via administration of a β - D-2'-methyl-ribofuranosyl nucleoside..

Dependent claims are drawn to including anti-hepatitis C agents with he

compound for the treatment of hepatitis C.

Dependent claims are also drawn to the dosage form as a capsule or tablet containing 50 - 1000 mg and a substantially pure form of the compound wherein the weight is at least 90% or 95% of the composition.

Bhat anticipates the claims as it teaches a 2' methyl, 3' hydroxy nucleoside compound and pharmaceutically acceptable salts thereof for the treatment of hepatitis C see columns 1-10. Bhat also teaches the use of additional agents in the treatment such as ribavirin, nucleotide analogs (polymerase inhibitors) and interferon (see col. 35, lines 10-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 130-143 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. 6,777,395, Bhat et al. (Bhat).

Claim 130 is drawn to a method for treating hepatitis C via administration of a β - D-2'-methyl-ribofuranosyl nucleoside.

Dependent claims are drawn to including anti-hepatitis C agents with he compound for the treatment of hepatitis C.

Dependent claims are also drawn to the dosage form as a capsule or tablet containing 50 - 1000 mg and a substantially pure form of the compound wherein the weight is at least 90% or 95% of the composition.

Bhat anticipates the claims as it teaches a 2' methyl-ribofuranosyl nucleoside nucleoside compound and pharmaceutically acceptable salts thereof for the treatment of hepatitis C (see columns 1-10). Bhat also teaches the use of additional agents in the treatment such as ribavirin, nucleotide analogs (polymerase inhibitors) and interferon (see col. 35, lines 10-40).

Bhat does not teach helicase inhibitors as an additional agent, however, the combination of two agents known in the art to have utility separately for the same disease is obvious.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to include a helicase inhibitor as an additional agent in the treatment of hepatitis C.

A person of ordinary skill in the art would have been motivated to combine a β - D-2'-methyl-ribofuranosyl nucleoside compound and a helicase inhibitor for the treatment of hepatitis C since the prior art has recognized the separate utility of these compounds to treat hepatitis C and the suggestion by the prior art to include additional anti-hepatitis C agents with the nucleoside compound for the treatment of hepatitis C.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.